Application

Docket No.: 10400-0000203/US

## IN THE CLAIMS

## 1-56 (Cancelled)

- 57. (New) A device for promoting regeneration of an injured nerve, comprising: a nerve encasement structure; and
- a plurality of biodegradable guiding units, wherein at least a majority of the guiding units present an in vivo degradation time  $t_1$  being less than a time  $t_c$  required for establishing regenerated contact between ends of an injured nerve using the device for said regeneration.
- 58. (New) A device according to claim 57, wherein at least a major part of the nerve encasement structure presents an in vivo degradation time  $t_2$  being longer than  $t_1$ .
- 59. (New) A device according to claim 58, wherein  $t_2$  is longer than a time  $t_r$  required for the entire nerve regeneration process to be completed.
  - 60. (New) A device for promoting regeneration of an injured nerve comprising: a biodegradable nerve encasement structure; and
- a plurality of biodegradable guiding units, wherein at least a majority of the guiding units present an in vivo degradation time  $t_1$ , at least a major part of the nerve encasement structure presents an in vivo degradation time  $t_2$ ,  $t_2$  being longer than  $t_1$  and longer than a time  $t_r$  required for the entire nerve regeneration process to be completed, and  $t_1$  being less than  $t_r$ .
- 61. (New) A device according to claim 60, wherein  $t_1$  is less than a time  $t_c$  required for establishing regenerated contact between the ends of an injured nerve using the device for said regeneration.
- 62. (New) A device according to claim 60, wherein the plurality of biodegradable guiding units are a plurality of biodegradable guiding fibres.
- 63. (New) A device according to claim 60, wherein the material of the nerve encasement structure and the material of the guiding units each comprises at least one biodegradable polymer.

64. (New) A device according to claim 63, wherein said at least one biodegradable polymer comprises at least one biodegradable polyester.

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- 65. (New) A device according to claim 64, wherein said at least one biodegradable polyester comprises PHB.
- 66. (New) A device according to claim 64, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding units comprises PHB.
- 67. (New) A device according to claim 64, wherein the material of the nerve encasement structure comprises PHB and the material of the guiding units comprises PLGA.
- 68. (New) A device according to claim 63, wherein said at least one polymer comprised in the material of the guiding units present an average molecular weight which is lower than an average molecular weight of said at least one polymer comprised in the material of the nerve encasement structure.
- 69. (New) A nerve regeneration device according to claim 68, wherein the material of the nerve encasement structure and the material of the guiding units each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.
- 70. (New) A device according to claim 69, wherein the PHB average molecular weight of the nerve encasement structure is within the range of from 100 000 to 250 000 and the PHB average molecular weight of the guiding units is within the range of from 50 000 to < 250 000.
- 71. (New) A device according to claim 57, wherein the nerve encasement structure comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.
- 72. (New) A device according to claim 57, wherein the plurality of guiding units are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.

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73. (New) A device according to claim 57, further comprising a hydrogel matrix.

- 74. (New) A device according to claim 57, further comprising at least one biologically active substance or cell.
- 75. (New) A device according to claim 74, wherein said at least one biologically active substance comprises a nerve growth promoting substance selected from the group consisting of nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).
- 76. (New) A device according to claim 74, wherein said at least one biologically active cell is selected from the group consisting of endothelial cells; fibroblasts; Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.
- 77. (New) A device according to claim 57, wherein a guiding unit occupies  $\leq$  2.0% by volume of the lumen formed by the nerve encasement structure.
- 78. (New) A device according to claim 57, wherein each guiding unit of a majority of the guiding units has a cross-sectional dimension  $\leq$  50  $\mu$ m.
- 79. (New) A device according to claim 78, wherein each guiding unit of a majority of the guiding units has a cross-sectional dimension  $\leq 20 \,\mu\text{m}$ .
- 80. (New) A device according to claim 79, wherein each guiding unit of a majority of the guiding units has a cross-sectional dimension within the range of from 5 to 15 µm.
- 81. (New) A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising:
  - a sheet: and
- a plurality of biodegradable guiding units, at least a majority of the guiding units present an in vivo degradation time  $t_1$  being less than a time  $t_c$  required for establishing

regenerated contact between the ends of an injured nerve using the device for said regeneration.

- 82. (New) A kit according to claim 81, wherein the sheet presents an in vivo degradation time  $t_2$  being longer than  $t_1$ .
- 83. (New) A kit for preparing a device for promoting regeneration of an injured nerve, said kit comprising:
  - a biodegradable sheet; and
- a plurality of biodegradable guiding units, wherein at least a majority of the guiding units present an in vivo degradation times  $t_1$ , at least a major part of the sheet presents an in vivo degradation time  $t_2$ ,  $t_2$  being longer than  $t_1$  and longer than a time  $t_r$  required for the entire nerve regeneration process to be completed, and  $t_1$  being less than  $t_r$ .
- 84. (New) A kit according to claim 81, wherein the plurality of biodegradable guiding units are a plurality of biodegradable guiding fibres.
- 85. (New) A kit according to claim 81, wherein the material of the sheet and the material of the guiding units each comprises at least one biodegradable polymer.
- 86. (New) A kit according to claim 85, wherein said at least one biodegradable polymer comprises at least one biodegradable polyester.
- 87. (New) A kit according to claim 86, wherein said at least one biodegradable polyester comprises PHB.
- 88. (New) A kit according to claim 86, wherein the material of the sheet comprises PHB and the material of the guiding units comprises PHB.
- 89. (New) A kit according to claim 86, wherein the material of the sheet comprises PHB and the material of the guiding unit comprises PLGA.
- 90. (New) A kit according to claim 85, wherein said at least one polymer comprised in the material of the guiding units present an average molecular weight which is

lower than an average molecular weight of said at least one polymer comprised in the material of the sheet.

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- 91. (New) A kit according to claim 90, wherein the material of the sheet and the material of the guiding units each comprises PHB having an average molecular weight within the range of from 50 000 to 500 000.
- 92. (New) A kit according to claim 91, wherein the PHB molecular weight of the sheet is within the range of from 100 000 to 250 000 and the PHB molecular weight of the guiding units is within the range of from 50 000 to < 250 000.
- 93. (New) A kit according to claim 81, wherein the sheet comprises a compressed non-woven sheet of biodegradable fibres having an essentially unidirectional fibre orientation.
- 94. (New) A kit according to claim 81, wherein the plurality of guiding units are biodegradable fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.
  - 95. (New) A kit according to claim 81, further comprising a hydrogel material.
- 96. (New) A kit according to claim 95, wherein the hydrogel is in a dehydrated state.
- 97. (New) A kit according to claim 81, further comprising at least one biologically active substance or cell.
- 98. (New) A kit according to claim 97, wherein said at least one biologically active substance comprises a nerve growth promoting substance selected from the group consisting of nerve growth factor (NGF); brain-derived neurotrophic factor (BDNF); neurotrophin-3 (NT-3); neurotrophin-4 (NT-4); glial growth factor (GGF); insulin-like growth factor (IGF); platelet-derived growth factor (PDGF); fibroblast growth factor (FGF); transforming growth factor (TGF); and epidermal growth factor (EGF).

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99. (New) A kit according to claim 97, wherein said at least one biologically active cell is selected from the group consisting of endothelial cells; fibroblasts; Schwann cells; olfactory ensheathing cells; stem cells or precursor cells thereof.

100. (New) A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, comprising:

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at least one surface at least partly coated with a dehydrated hydrogel material; and a plurality of biodegradable guiding units, wherein at least a majority of the guiding units presents an in vivo degradation time t<sub>1</sub> being less than a time t<sub>c</sub> required for establishing regenerated contact between the ends of an injured nerve using device.

101. (New) A biodegradable sheet for preparing a device for promoting regeneration of an injured nerve, comprising:

at least one surface at least partly coated with a dehydrated hydrogel material; and a plurality of biodegradable guiding units, wherein at least a majority of the guiding units presents an in vivo degradation time  $t_1$ , at least a major part of the sheet presents an in vivo degradation time  $t_2$ ,  $t_2$  being longer than  $t_1$  and longer than a time  $t_r$  required for the entire nerve regeneration process to be completed , and  $t_1$  being less than  $t_r$ .

- 102. (New) A biodegradable sheet according to claim 101, wherein the plurality of biodegradable guiding units are a plurality of biodegradable guiding fibres.
- 103. (New) A biodegradable sheet according to claim 100, said dehydrated hydrogel material further comprising at least one biologically active substance or cell.
  - 104. (New) A method, comprising:

using a plurality of biodegradable guiding units for promoting regeneration of an injured nerve, wherein at least a majority of the guiding units presents an in vivo degradation time  $t_1$  being less than a time  $t_c$  required for establishing regenerated contact between the ends of an injured nerve using the guiding units for said regeneration.

105. (New) A method according to claim 104, wherein the plurality of biodegradable guiding units are a plurality of biodegradable guiding fibres.

106. (New) A method according to claim 104, wherein the material of the guiding units comprises at least one biodegradable polymer.

- 107. (New) A method according to claim 106, wherein said at least one biodegradable polymer comprises at least one biodegradable polyester.
- 108. (New) A method according to claim 107, wherein said at least one biodegradable polyester comprises PHB.
- 109. (New) A method according to claim 107, wherein said at least one biodegradable polyester comprises PLGA.
- 110. (New) A method according to claim 108, wherein PHB has an average molecular weight within the range of from 50 000 to 250 000.
- 111. (New) A method according to claim 104, wherein the guiding units are fibres in the form of a non-bonded fibre web having an essentially unidirectional fibre orientation.
- 112. (New) A method for promoting regeneration of an injured nerve, comprising the step of applying, at said injured nerve, a device according to claim 57.